Standard Guide for Gravimetric Wear Assessment of Prosthetic Hip-Designs in Simulator Devices[1]

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1. Scope

1.1 This guide describes a laboratory method using a weight-loss technique for evaluating the wear properties of materials or devices, or both, which are being considered for use as bearing surfaces of human-hip-joint replacement prostheses. The hip prostheses are evaluated in a device intended to simulate the tribological conditions encountered in the human hip joint, for example, use of a fluid such as bovine serum, or equivalent pseudosynovial fluid shown to simulate similar wear mechanisms and debris generation as found in vivo, and test frequencies of 1 Hz or less.

1.2 Since the hip simulator method permits the use of actual implant designs, materials, and physiological load/motion combinations, it can represent a more physiological simulation than basic wear-screening tests, such as pin-on-disk (see Practice F 732) or ring-on-disk (see ISO-6474).

1.3 It is the intent of this guide to rank the combination of implant designs and materials with regard to material wear-rates, under simulated physiological conditions. It must be recognized, however, that there are many possible variations in the in vivo conditions, a single laboratory simulation with a fixed set of parameters may not be universally representative.

1.4 The reference materials for the comparative evaluation of candidate materials, new devices, or components, or a combination thereof, shall be the wear rate of extruded or compression-molded, ultra-high molecular weight (UHMW) polyethylene (see Specification F 648) bearing against standard counter faces [stainless steel (see Specification F 138); cobalt-chromium-molybdenum alloy (see Specification F 75); thermomechanically processed cobalt chrome (see Specification F 799); alumina ceramic (see Specification F 603)], having typical prosthetic quality, surface finish, and geometry similar to those with established clinical history. These reference materials will be tested under the same wear conditions as the candidate materials.

2. Referenced Documents

2.1 *ASTM Standards:*

D 883 Terminology Relating to Plastics[2]

F 75 Specification for Cast Cobalt-Chromium-Molybdenum Alloy for Surgical Implant Applications[3]

F 86 Practice for Surface Preparation and Marking of Metallic Surgical Implants[3]

F 136 Specification for Titanium 6A1-4V ELI Alloy for Surgical Implant Applications[3]

F 138 Specification for Stainless Steel Bar and Wire for Surgical Implants (Special Quality)[3]

F 370 Specification for Proximal Femoral Prosthesis[3]

F 565 Practice for Care and Handling of Orthopedic Implants and Instruments[3]

F 603 Specification for High-Purity Dense Aluminum Oxide for Surgical Implant Application[3]

F 648 Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants[3]

F 732 Practice for Pin-on-Flat Evaluation of Friction and Wear Properties of Polymeric Materials for Use in Total Joint Prostheses[3]

F 799 Specification for Thermomechanically Processed Cobalt-Chrome-Molybdenum Alloy for Surgical Implants[3]

G 40 Terminology Relating to Erosion and Wear[4]

2.2 *ISO Standard:*

ISO 6474 Implants for Surgery–Ceramic Materials Based on Alumina[5]

3. Significance and Use

3.1 This guide uses a weight-loss method of wear determination for the polymeric components used with hip-joint prostheses, using serum or demonstrated equivalent fluid for lubrication, and running under a dynamic load profile representative of the human hip-joint forces during walking **(1,2)**.[6] The basis for this weight-loss method for wear measurement was originally developed **(3)** for pin-on-disk wear studies (see Practice F 732) and has been extended to total hip replacements **(4,5)** and to femoral-tibial knee prostheses **(6)**, and to femoropatellar knee prostheses **(6,7)**.

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[2] *Annual Book of ASTM Standards*, Vol 08.01.

[3] *Annual Book of ASTM Standards*, Vol 13.01.

[4] *Annual Book of ASTM Standards*, Vol 03.02.

[5] Available from American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036.

[6] The boldface numbers in parentheses refer to the list of references at the end of this standard.

3.2 While wear results in a change in the physical dimensions of the specimen, it is distinct from dimensional changes due to creep or plastic deformation, in that wear generally results in the removal of material in the form of polymeric debris particles, causing a loss in weight of the specimen.

3.3 This guide for measuring wear of the polymeric component is suitable for various simulator devices. These techniques can be used with metal, ceramic, carbon, polymeric, and composite counter faces bearing against a polymeric material (for example, polyethylene, polyacetal, and so forth). This weight-loss method, therefore, has universal application for wear studies of total-hip replacements that feature polymeric bearings. This weight-loss method has not been validated for high-density material bearing systems, such as metal-metal, carbon-carbon, or ceramic-ceramic. Progressive wear of such rigid bearing combinations generally has been monitored using a linear, variable-displacement transducers or by other profilometric techniques.

4. Apparatus and Materials

4.1 *Hip Prosthesis Components*—The hip-joint prosthesis comprises a ball-and-socket configuration in which materials such as polymers, composites, metal alloys, ceramics, and carbon have been used in various combinations and designs.

4.2 *Component Configurations*—The diameter of the prosthetic ball may vary from 22 to 54 mm or larger. The design may include ball-socket, trunnion, bipolar, or other configurations.

4.3 *Hip Simulator*:

4.3.1 *Test Chambers*—In the case of a multi-specimen machine, contain the components in individual, isolated chambers to prevent contamination of one set of components with debris from another test. Ensure that the chamber is made entirely of noncorrosive materials, such as acrylic plastic or stainless steel, and is easily removable from the machine for thorough cleaning between tests. Design the wear chambers such that the test bearing surfaces are immersed in the lubricant throughout the test **(3,7)**.

4.3.2 *Component Clamping Fixtures*—Since wear is to be determined from the weight loss of the components, the method for mounting the components in the test chamber should not compromise the accuracy of assessment of the weight-loss due to wear.

4.3.3 *Load*—Ensure that the test load profile is representative of that which occurs during the patients walking cycle, with peak hip-loads ≥ 2 kN **(2)**. The loading apparatus must be free to follow the specimen as wear occurs, such that the applied load is constant to within ± 3 % for the duration of the test. Never allow the applied load to be below that required to keep the chambers seated (for example, 50 N) **(4)**.

4.3.4 *Motion*—Ensure that relative motion between the hip components oscillates and simulates the flexion-extension arc of walking. Addition of internal-external or abduction-adduction arcs is at the investigator's discretion. It is recommended that the orientations of the cup and ball relative to each other and to the load-axis be maintained by suitable specimen-holder keying.

4.3.5 *Oscillating Frequency*—Oscillate the hip prostheses at a rate of one cycle per second (1 Hz).

4.3.6 *Cycle Counter*—Include a counter with the hip-simulator to record the total number of wear cycles.

4.3.7 *Friction*—It is recommended that the machine include sensors capable of monitoring the friction forces transmitted across the bearing-surfaces during the wear test.

4.4 *Lubricant*:

4.4.1 It is recommended that the specimen be lubricated with bovine blood serum, however, another suitable lubrication medium may be used if validated.

4.4.2 If serum is used, then use filtered-sterilized serum rather than pooled serum since the former is less likely to contain hemolyzed blood material, which has been shown to adversely affect the lubricating properties of the serum **(3)**. Diluted solutions of serum also have been used for this purpose **(8)**. Filtration may remove hard, abrasive, particulate contaminants that might otherwise affect the wear properties of the specimens being tested.

4.4.3 Maintain the volume and concentration of the lubricant nearly constant throughout the test. This may be accomplished by sealing the chambers so that water does not evaporate, or periodically or continuously replacing evaporated water with distilled water.

4.4.4 To retard bacterial degradation, freeze and store the serum until needed for test. In addition, ensure that the fluid medium in the test contains 0.2 % sodium azide (or other suitable antibiotic) to minimize bacterial degradation. Other lubricants should be evaluated to determine appropriate storage conditions.

4.4.5 It is recommended that ethylene-diaminetetraacetic acid (EDTA) be added to the serum at a concentration of 20 mM to bind calcium in solution and minimize precipitation of calcium phosphate onto the bearing surfaces. The latter event has been shown to strongly affect the friction and wear properties, particularly of polyethylene/ceramic combinations. The addition of EDTA to other lubricant mediums should be evaluated.

4.4.6 A lubricant other than bovine serum may be used when it can be shown that its lubricating properties and, therefore, material wear properties are reasonably physiological **(8)**. In such a case, specify the lubricant in the test report.

4.5 Hold the bulk temperature of the lubricant at 37 ± 3°C or specified, if different.

5. Specimen Preparation

5.1 The governing rule for preparation of component counter faces is that the fabrication process parallels that used or intended for use in the production of actual prostheses, in order to produce a specimen with comparable bulk material properties and surface characteristics (see Practice F 86).

5.2 *Polymers and Composites*:

5.2.1 Obtain a fabrication history for each polymeric or composite component, including information such as grade, batch number, and processing variables, including method of forming (extruding, molding, and so forth), temperature, pressure, and forming time used, and any post-forming treatments, including sterilization.

5.2.2 Pretest characterization may include measurement of bulk material properties, such as molecular-weight range and distribution, percent crystallinity, density, or other. The surface finish of specimens may be characterized by profilometry, photomicrography, replication by various plastics, or other techniques.

5.2.3 *Sterilization*—Sterilize the components in a manner typical of that in clinical use for such devices, including total dose and dose rate, as these may affect the wear properties of the materials. Report these processing parameters with the aging time prior to each test when known. Sterilization of all test and control components within a specific test group should be done simultaneously (in a single container), when possible, to minimize variation among the specimens. This wear-simulation procedure makes no attempt to maintain the sterility of specimens during the wear test.

5.2.4 *Cleaning of Polymer Prostheses*—Prior to wear testing, careful cleaning of the polymer specimens is important to remove any contaminants that would not normally be present on the actual prosthesis. During the wear run, the components must be re-cleaned and dried before each weighing to remove any extraneous material that might affect the accuracy of the weighing. A suggested procedure for cleaning and drying of polymeric components is given in Annex A4. With some combinations of materials, wear may result in the transfer of particulate debris which may then become reimbedded or otherwise attached to polymeric, metal, or composite surfaces. Such an occurrence will render the weight-loss assessment of wear less reliable.

5.2.5 *Weighing of Polymeric Components*—Weigh the polymeric components on an analytical balance having an accuracy on the order of± 10 µg. This degree of sensitivity is necessary to detect the slight loss in weight of polymers, such as UHMW polyethylene, which may wear 30 mg or less per million cycles **(3,5)**. Always weight specimens in the clean, dry condition (see Annex A1). Keep the components in a dust-free container and handle with clean tools to prevent contamination that might affect the weight measurement. Weigh each wear and control component three times in rotation to detect random errors in the weighing process.

5.3 *Soaking of Polymeric and Composite Prostheses*:

5.3.1 Polymeric and composite components should be presoaked in the lubricant to minimize fluid-sorption during the wear run. Without presoaking, components of very low-wear polymers such as polyethylene may show a net increase in weight during the initial wear intervals, due to fluid sorption **(3,4)**. The error due to fluid sorption can be reduced through presoaking and the use of control soak specimens. The number of specimens required and the length of presoaking depends on the variability and magnitude of fluid sorption encountered **(4)**.

5.3.2 After fabrication and characterization, clean and dry the wear components and three soak-control components of each test material in accordance with Annex A4, and then weigh by precisely controlled and repeatable methods. Place the wear components and soak controls in a container of serum for a specified time interval. Then, remove, clean, dry, and reweigh the components, and calculate the weight (see Annex A4). Repeat the specimens until a steady rate of fluid-sorption has been established. The number of weighings will depend on the amount of fluid sorption exhibited by the specimens.

5.3.3 In general, the weight of the components will stabilize at an asymptotic value in a reasonable time period. With UHMW polyethylene, a presoak period of 30 days has been found adequate **(4,7)**. In any case, use the weight gain of the soak controls to correct for ongoing fluid sorption by the wear components during the wear test.

5.4 *Counterfaces of Metal Alloys, Ceramic, or Other Materials*:

5.4.1 *Characterization*—Include with the pretest characterization of metal, ceramic, or other materials, recording of fabrication variables, such as composition, forming method (forging, casting, and so forth) and any postforming processing, such as annealing. Obtain data on material properties relevant to wear (for example, grain structure, hardness, and percentage of contaminants).

5.4.2 *Surface Finish*—In tests that are intended to evaluate an alternate counter face material bearing against the standard UHMWPE, ensure that the counter face finish is appropriate for components intended for clinical use. In tests of alternate materials where a reference metal or ceramic is used, polish the counter face to the prosthesis quality.

5.4.3 Clean, degrease, and passivate components of referenced prosthetic metals or ceramics in accordance with Practice F 86. This practice may require modification for components of other materials. Ensure that cleaning of components produces a surface free of any particles, oils, greases, or other contaminants that might influence the wear process.

6. Measurement Procedure

6.1 At the completion of the presoak period, the wear components and soak controls should be removed from the soak bath, cleaned, dried, and weighed by precisely controlled and repeatable methods. Record these weights as the initial weights of the specimens for purposes of calculating the progressive weight loss during the wear test. Place the three soak control specimens in holders in a soak chamber of test lubricant, such that the total surface area exposed to the lubricant is equal to that of the wear components when mounted in the hip simulator. Maintain the soak chamber temperature at 37 ± 3°C, or specify if different. It is recommended that the soak chamber be attached to the simulator or otherwise agitate in the same manner as the actual wear chambers. In addition, it may be advantageous to apply a cyclic load to the soak control specimens (without tangential motion) comparable to that applied to the wear specimens, since this also can affect the rate of fluid sorption.

6.2 Frictional torque should be recorded for each specimen combination. This may be done in a preliminary test under a constant (static) load, or during the wear test under the cyclic, physiological load. These measurements may be repeated at various intervals during the wear test to determine changes in frictional properties with progressive wear.

6.3 Place the wear test components in the hip simulator, add the lubricant, apply the load, and commence the cyclic motion. Record the frictional force simultaneously with the wear cycling, where applicable.

6.4 Matching of components in each test set may be desirable to ensure optimum consistency of wear performance doing these tests.

6.5 As testing is commenced, monitor the components for signs of erratic behavior that might require an early termination of the test.

6.6 Remove the wear and soak components at specified intervals, wash, rinse, and dry concurrently, in accordance with the procedure in Annex A4. It is important that both the wear and soak components be treated identically to ensure that they have the same exposure to the wash, rinse, and drying fluids. This will provide the most accurate correction for fluid sorption by the wear specimens.

6.7 After rinsing and drying, weigh the wear components and soak controls on the analytical balance as described in 5.2.5.

6.8 Thoroughly rinse the wear chambers and component surfaces with distilled water.

6.9 Inspect the bearing surfaces of the hip components and note the characteristics of the wear process. Visual, microscopic, profilometric, replication, or other inspection techniques can be used. Care must be taken, however, that the surfaces do not become contaminated or damaged by any substance or technique that might affect the subsequent wear properties. If contamination occurs, thoroughly reclean the specimens prior to restarting the wear test.

6.10 Replace the wear components and soak controls in fresh lubricant and continue wear cycling.

7. Determining Wear Rates

7.1 *Test Length*—The accuracy of the test method depends on the relative magnitudes of wear and fluid sorption. This is especially true when the fluctuations in the weight due to variation in the amount of surface drying are large in comparison to the incremental weight-loss due to wear. For high-wear low-sorption materials, the wear rate may be established clearly in as few as 50 000 wear cycles. With comparatively low-wearing materials, such as UHMWPE, several million cycles or more may be required to clearly establish the long-term wear properties.

7.2 *Number of Replicate Tests*—Perform tests intended to determine the relative wear rates of two materials with at lest three sets of specimens for each material to provide an indication of the repeatability of the results. As for any such experimental comparison, the total number of specimens eventually needed will depend on the magnitude of the difference to be established, the repeatability of the results (standard deviation), and the level of statistical significance desired.

7.3 *Correcting for Fluid Sorption*—Add to or subtract from the average weight gain (or loss) of the three soak control components the measured weight loss of each wear component (see Annex A6). This procedure corrects both for systematic sorption, as well as random differences in the amount of surface drying (of the entire set of test and control specimens) at each interval of weighing.

7.4 *Conversion to Volumetric Wear*—In tests where the wear rates of materials with different densities are evaluated, it may be preferable to compare these on the basis of volumetric wear, rather than weight loss. It is preferable that comparisons of the wear properties between components of polymeric materials having different densities be done on the basis of volumetric wear. The volumetric wear rate may be obtained by dividing the weight-loss data by the density of the material, in appropriate units. The accuracy of this calculation is dependent on the material being reasonably homogeneous, that is, having a constant density with wear depth. Report the density value used in this conversion.

8. Report

8.1 *Materials*:

8.1.1 Provide material traceability information from a raw material and fabrication or manufacturing standpoint for each material counter face. Examples of such information include material grade, batch number, and processing variables.

8.1.2 Pretest characterization for a plastic counter face may include measurement of bulk material properties, such as molecular-weight average, range and distribution, percent crystallinity, density, degree of oxidation, or others. The surface finish of both counter faces may be characterized by profilometry, photomicrography, replication, or other applicable techniques.

8.1.3 Report the method of sterilization, the sterilization and test dates, and the means of storage post-sterilization and pretest.

8.2 *Loading Conditions*—Describe the loading conditions used on the specimens. Report load curves and motions and timing relationships.

8.3 *Wear Rates*:

8.3.1 Graphically plot the weight loss of each specimen as a function of wear cycles. Wear may be reported as the weight loss of the bearing component as a function of the number of wear cycles, but it also may be converted to volumetric wear if the density of the material is known.

8.3.2 In tests where the wear rate is nearly constant over the test run, calculate the volumetric wear rate by the method of least squares in each regression.

8.3.3 If the wear rate changes during the test, as with a decrease due to wearing-in of the specimens or an increase due to the onset of fatigue wear, linear regression may be applied to separate intervals of the test to indicate the change in wear rate.

8.3.4 At the discretion of the investigator, more complex, nonlinear models may be fit to the wear-test data.

8.3.5 Report the test duration in cycles.

8.4 *Accuracy and Repeatability*:

8.4.1 In multiple tests where the wear rate is determined from the slope of the graph comparing wear versus test duration (cycles) for each specimen, report the individual rates, mean wear rate, and the 95 % confidence intervals for each rate.

8.4.2 In cases where the mean wear rate for two materials is different, evaluate and report the level of statistical significance of this difference.

8.5 Since the accumulation of wear debris in the lubricant may influence the wear rate, report any filtering of the lubricant during operation (continuously or periodically).

8.6 Record and report the room temperature and humidity during each weighing session.

8.7 Report the loading conditions on the soak control specimens. Load soaking, which is defined as a pulsing load profile equivalent to the wear profile without the tangential movement, has been shown to increase the fluid sorption rate.

8.8 In order that the simulator wear data be reproducible and comparable among laboratories, it is essential that uniform procedures be established. Sufficient data has not yet been produced using identical materials in different laboratories to permit determining the precision and bias of this recommended procedure. This guide is intended, in part, to facilitate uniform testing and reporting of data from hip joint simulator wear studies. It is anticipated that the references provided will permit validation of this methodology.

ANNEXES

(Mandatory Information)

A1. CHOICE OF WEAR-TEST LUBRICANT

A1.1 Comparative experiments have shown that distilled water or saline solutions do not duplicate the lubricating properties of fluids such as serum or synovial fluid that contain physiological concentrations of proteins **(1,3)**. In particular, the heavy transfer of polyethylene to the surface of metal or ceramic implant that is typically observed with water or saline lubrication, is not typical of serum-lubricated specimens and is not typical of retrieved components after extended use in vivo. Care must be taken in the choice of lubricant to ensure that when used in simulated hip wear tests, it approximates the wear found clinically. Report the choice of lubricant along with the validation for its use.

A2. IMPLANT MATCHING FOR CONSISTENT WEAR PERFORMANCE

A2.1 The optimal clearance between the ball and socket of total hip prostheses is a matter of controversy with regard to its affect on the friction and wear properties, and this will vary for different combinations of materials and different designs of prostheses **(5,7,9)**. It may be desirable to calculate the effects of design and installation procedures on frictional forces across the material components prior to performing an extended wear study.

A3. PRECAUTIONS IN PREPARING SPECIMEN SURFACES

A3.1 Do not polish or otherwise attempt to improve the polymer surfaces with abrasives, for example, aluminum oxide. Particles of the polishing compound may remain embedded in the polymeric material and could strongly affect the wear performance of the bearing materials.

A4. METHOD FOR CLEANING OF SPECIMENS

A4.1 Gently scrub cups with a nonabrasive material to remove all serum particles. Verify under a magnifying glass.

A4.2 Rinse under a stream of deionized water.

A4.3 Clean in an ultrasonic cleaner:

A4.3.1 Five minutes in deionized, particle-free water.
A4.3.2 Rinse in deionized water.
A4.3.3 Ten minutes in 10 mL of liquid ultrasonic cleaning detergent plus 500 mL of water.
A4.3.4 Rinse in deionized water.
A4.3.5 Ten minutes in deionized water.
A4.3.6 Rinse in deionized water.
A4.3.7 Three minutes in deionized water.
A4.3.8 Rinse in deionized water.

A4.4 Dry with a jet of nitrogen or suitable clean, dry gas.

A4.5 Soak in 95 % methyl alcohol for 5 min.

A4.6 Dry with a jet of nitrogen or suitable gas.

A4.7 Dry in a vacuum jar at a minimum vacuum 10^{-3} torr for 30 min.

A4.8 Weigh on a microbalance.

A4.9 To minimize weighing errors, weigh the entire set of specimens three times, in rotation, keeping the same specimen sequence each time. Polymeric cups typically gain or lose weight slightly between each weighing due to additional sorption or evaporation of fluid. The average of the three weights may be used for the wear calculations.

NOTE A4.1—This is a suggested cleaning procedure suitable for metals, ceramics, carbon, and UHMW polyethylene (3). Use methyl alcohol only for polymers that are essentially insoluble in this liquid. For polymers that dissolve or degrade in methyl alcohol, substitute a more appropriate volatile solvent. The purpose of this step is to remove the water from the surface layer of the specimen that otherwise tends to evaporate during the weighing process. Other aspects of this procedure might require modification for the particular polymer being tested.

A5. COMPONENT CLAMPING FIXTURES

A5.1 One technique that has proven practical has been to clamp each component in a mold (for example, polyurethane) that replicates the outer shape of the test component. The mounting mold is then press-fit into the stainless steel base of each chamber (7). The mounting method should permit the test components to be removed periodically for cleaning and weighing without damaging the test components or causing a separate loss of weight of the test components. If there is doubt, it is recommended that several specimens be mounted and removed from the machine several times each and weighted each time to detect any weight change caused by the mounting procedure.

A6. CALCULATION OF SPECIMEN WEAR

A6.1 The amount of fluid sorption over a wear interval is determined from the three soak controls, whereby the average weight gain, Sn, is calculated as follows:

$$Sn = 1/3\,(Sa + Sb + Sc) \tag{A6.1}$$

A6.2 Since fluid sorption by the wear specimens tends to mask the actual weight loss due to wear, increase the magnitude of the measured weight loss by the wear specimens by the magnitude of the weight-gain of the soak specimens. Where S1 equals initial average weight of the three soak specimens and S2 equals the final average weight of the three soak specimens.

A6.3 The actual net wear, then, is given as follows:

$$Wn = W1 - W3 \tag{A6.2}$$

A6.3.1 However, W3 is unknown. On the other hand, the apparent wear is given as follows:

$$Wa = W1 - W2 \tag{A6.3}$$

where:

$W1$ = initial weight of the wear specimen,
$W2$ = final weight of the wear specimen (including a gain due to fluid sorption), and
$W3$ = the actual final weight of the wear specimen if fluid sorption is subtracted out.

A6.3.2 The actual net wear (Wn) can be obtained by increasing the apparent wear (Wa) by an amount equal to the net soak gain.

$$\text{Wn} = \text{Wa} + \text{Sn; Where Sn} = S2 - S1 \tag{A6.4}$$

$$\text{Thus Wn} = (W1 - W2) + (S2 - S1) \tag{A6.5}$$

A6.4 Note that the four weights W1, W2, S1, and S2 are actual measured values. The sign convention in this equation for Wn takes into account occurrences, such as an apparent weight gain by the wear specimen (giving a negative value for Wa) or a net weight loss by the soak specimens (a negative value of Sn). In most cases the net wear, Wn, will be zero or positive.

A6.5 The net volumetric wear is then given as follows:

$$Vn = Wn/p \tag{A6.6}$$

where:

p = density of the polymer, expressed in appropriate units.

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 The hip simulator wear studies of materials may involve three types of evaluation:

X1.1.1 Comparing the wear rate of a candidate polymeric material to that of polyethylene, both bearing against one of the reference metal or ceramic counter faces..

X1.1.2 Comparing the polyethylene wear on the candidate counter face material to that of polyethylene wear on the reference metal or ceramic component.

X1.1.3 Comparing the wear rate of a new combination of candidate materials to the reference combinations.

X1.2 For the purpose of this guide, wear is defined as the progressive loss of material from a prosthetic component as a result of tangential motion against its mating component under load. For current designs of total hip prostheses, used since 1971 in the United States, the polymeric component bearing against metal, ceramic, composite, or carbon balls will be the sacrificial member, that is, the polymer will be the predominant source of wear debris. The metallic or other non-polymeric components, however, also may contribute either ionic or particulate debris. Depending on circumstances, therefore, wear may be generated by adhesion, two or three body abrasion, surface or subsurface fatigue, or some other process. Depending on the candidate materials and design combinations selected, it may be desirable in some instances to add additional techniques to identify the nature and magnitude of the wear process.

X1.3 While wear results in a change in the physical dimensions of the specimen, it is distinct from dimensional changes due to creep or plastic deformation in that wear generally results in the removal of material in the form of debris particles, causing a loss in weight of the specimen **(3, 7)**.

X1.4 Wear rate is the gravimetric or volumetric wear per million cycles of test.

X1.5 During wear testing in serum, calcium phosphate may precipitate on the surface of the test balls, particularly those of ceramic, and strongly affect the friction and wear properties. The addition of 20 mM EDTA in the lubricant may eliminate such precipitation.

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